

# Chapter 159 of the Acts of 2014

*An Act Relative to Pharmacy Practice in the  
Commonwealth*

Overview-Presented by

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# **Division of Health Professions** **Licensure**

The **Division of Health Professions Licensure (HPL)** is a Division under the **Bureau of Health Care Safety and Quality**. It is comprised of nine (9) Boards of Registration:

1. **Community Health Workers**
2. **Dentistry**
3. **Genetic Counselors**
4. **Nursing**
5. **Nursing Home Administrators**
6. **Perfusionists**
7. **Pharmacy**
8. **Physician Assistants**
9. **Respiratory Care**

# HPL Staffing and Budget

As of July 1, 2014

HPL licensed, registered, certified or authorized approximately:

- **199,000** health care professionals and businesses

Budget:

- approximately **\$12 million** dollars

Staffing level:

- approximately **75 full-time equivalent active staff**

During FY14:

- Boards resolved **628 formal complaints** against health professional/facility licenses
- **36% (226)** of formal complaints were resolved by imposition of **disciplinary action**

# National Fungal Meningitis Outbreak

Following the 2012 national fungal meningitis outbreak tied to New England Compounding Center (“NECC”), Governor Patrick directed the Board to undertake a comprehensive approach to improving state oversight of the compounding pharmacy industry in Massachusetts.

Governor Patrick also convened a Special Commission on the Oversight of Compounding Pharmacies, charging them to analyze the needs and gaps of the industry in order to formulate recommendations on necessary policy, regulatory and legislative changes.

# Governor Patrick's Initial Legislation

Leveraging the Commission's ensuing recommendations, Governor Patrick introduced legislation to implement several long-term reforms and address critical gaps in state oversight by:

- Establishing a **special license** for sterile compounding practice
- Empowering the Board to assess **fines**
- Enhancing “**whistleblower**” protection
- Establishing an out-of-state, **non-resident license**
- Authorizing the Board to create **additional specialty licenses** as necessary
- Restructuring the **composition of the Board**, including more members not practicing in the industry or “business type” they are responsible for regulating

## **Board's Response**

Multiple regulatory, monitoring, enforcement, training and other administrative efforts have been undertaken by the Board since fall 2012 to aggressively address the compounding pharmacy challenges.

They include but are not limited to:

# Board's Response

- Promulgation of **emergency regulations** in November 2012
- The first wave of **unannounced inspections** of all sterile compounding pharmacies
- Utilized its **cease and desist** authority to stop dangerous activity immediately
- Increased its compounding pharmacy related **investigator training**

# **Chapter 159 of the Acts of 2014**

## ***An Act Relative to Pharmacy Practice in the Commonwealth***

### **Summary**

Chapter 159 of the Acts of 2014, *An Act Relative to Pharmacy Practice in the Commonwealth* takes several significant steps to improve the delivery and oversight of pharmacy services in the Commonwealth.



# Strengthening Pharmacy Board Composition

*Chapter 159* sets a **13 member board** with:

- 8 pharmacists- (from 5 specific pharmacy fields)
- 1 pharmacy technician
- 1 public member with health care experience
- 1 physician
- 1 nurse
- 1 expert in patient safety and quality improvement

# Improving Pharmacy Licenses and Terms

*Chapter 159* requires the following **new licensure categories**:

- Retail Sterile Compounding License
- Retail Complex Non-Sterile Compounding License
- Institutional Sterile Compounding License
- Non-Resident or "Out-of-State" Pharmacy License

Hospital or "institutional pharmacies," which have not been previously regulated by the Pharmacy Board, will now be required to obtain a separate pharmacy license if they engage in sterile compounding.

The bill also permits the Board to establish specialty licensure categories **beyond** these listed licenses.

# Strengthening Penalties and Fines

*Chapter 159* establishes the authority of the board to assess a licensed pharmacy a fine of not more than **\$25,000** for each violation of regulations.

The board may also assess a licensed pharmacy a fine of not more than \$1,000 for **each violation** for **each day** the violation persists.

The board may also assess a fine of not more than \$1,000 for failure to provide documentation demonstrating compliance with **continuing education requirements**.

The board must provide licensee notice and **opportunity for a hearing** within fifteen (15) days regarding the assessment.

# Requiring Reporting of Serious Adverse Drug Events (SADE) and Recalls

Pharmacies must report any serious adverse drug events, including serious injury or death, related to a patient's use, consumption, or interaction with any pharmaceutical or drug preparation to:

- Department of Public Health
- Board of Pharmacy
- Food and Drug Administration's (FDA) MedWatch Program
- Betsy Lehman Center

# Recall of Compounded Products

*Chapter 159* requires pharmacies to **recall** compounded products that are defective in any way and to:

- immediately **recall** the drug preparation
- any of the same drug preparations must be **segregated** and **shall not** be **distributed** or **dispensed**
- a defective **drug preparation log** documenting the recalled drug preparation shall be kept by the pharmacy

# Improving Labeling Requirements

Pharmacies **must affix a label** to all sterile compounded and complex non-sterile compounded drug preparations notifying users and practitioners that the drug is either a **sterile or non-sterile compounded drug preparation.**

# Setting Continuing Education Requirements

Each registered pharmacist seeking renewal must complete at least **20 contact hours** of continuing education per year.

Pharmacists engaged in **sterile** compounding must complete at least **5 of the 20** contact hours of continuing education in the area of sterile compounding.

Pharmacists engaged in **complex non-sterile** compounding must complete at least **3 of the 20** contact hours of continuing education in the area of complex non-sterile compounding.

# Enhancing Oversight of Sterile and Complex Non-Sterile Compounding

*Chapter 159* contains several provisions for **enhancing oversight** of sterile and complex non-sterile compounding including:

- compounding pharmacies must **comply with** the current standards established by **USP**
- the board shall establish **inspectional criteria** for sterile and complex non-sterile compounding pharmacies
- the board shall promulgate **supplementary regulations** to enhance safety of sterile and non-sterile compounding activities



# Advisory Committee

*Chapter 159* establishes an **advisory committee** to investigate emerging models of coordinated, remote, and shared pharmacy services, including:

- central fill pharmacies
- existing or potential shortages of medically necessary drug products and recommend to the board options available to the commonwealth to mitigate the impact of drug shortages

# Transparency

*Chapter 159* includes several provisions to promote **transparency**, including:

- a searchable website which includes information pertaining to enforcement actions against licensees and serious adverse drug events
- an annual report prepared by the board and submitted to the department of public health, the joint committee on public health, and the joint committee on health care financing, summarizing complaints and disciplinary actions

# Next Steps

- **Implementation** of Chapter 159 mandates will occur in stages; beginning immediately, and continuing throughout FY15.
- Many of these stages, or “steps” will involve writing **new or revising existing regulations**, and will require specific actions, including;
  - Board approval to go forward for public comment
  - subsequent revision if necessary
  - final Board approval.

# Next Steps-Outreach

**Early stakeholder involvement** has been a key component of HPL's implementation strategy.

- Feedback prior to Board voting will allow stakeholders to be **part of the process**.
- It will insure the practicality of the regulations in a **real world setting**.
- Stakeholder involvement will help ensure **better understanding** and **compliance** among our licensees moving forward.

Thank you.

Questions?